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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,395

09/22/2003

John Butler

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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

11/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,395	Applicant(s) BUTLER ET AL.	
	Examiner Anu Ramana	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,14-25,27-36,55-58 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 9,17-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8,14-16,55-58 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 14, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-8, 14-16 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, the recitation "substantially continuously around the distal ring" implies the presence of gaps or discontinuities, not supported by applicant's disclosure, as originally filed.

In claim 58, the recitation "taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position" is not consistent with Figs. 43-46. Fig. 43 shows the insertion tool to be tapered towards a distal end of the insertion tool along a longitudinal axis of the insertion tool. Further, when the distal ring is engaged with the insertion tool, a plane containing a top surface of the distal ring intersects a plane containing the longitudinal axis of the insertion tool.

Art Unit: 3775

It is suggested that Applicant amend the claim to recite these features, in order to overcome this rejection. Please also refer to the rejection under 35 USC 112 second paragraph below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-8, 14-16, 55-58 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation "extends generally in a longitudinal direction with respect to the insertion tool" renders the claim vague and indefinite because it isn't clear what the "longitudinal direction" is. Is it a direction along a longitudinal axis of the insertion tool?

In claim 55, the phrase "facing distally away from the insertion tool" is confusing. It is suggested that Applicant amend this to recite "a opening with a closed end and an open end, the open end facing towards the distal end of the insertion tool."

In claim 58, the recitation "the distal ring extends generally in a longitudinal direction with respect to the insertion tool; and a taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position" does not clearly recite the structural relationship between the distal ring and the insertion tool. What is the "longitudinal direction?" Is it a direction along a longitudinal axis of the insertion tool? Appropriate correction is required.

It is suggested that applicant amend the claim to clarify the term "engaged position" to be the position in which the insertion tool engages the distal ring. Please also refer to the comments with respect to the rejection under 35 USC 112 first paragraph above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-8, 14, 55-57, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller et al. (US 5,810,721).

Mueller et al. disclose a retractor including: a retracting member 96 extending substantially continuously around a distal ring member 82 mounted to the retracting member, the distal ring member 82 being made of a flexible material; and an obturator or insertion tool 88 wherein the insertion tool 88 has a channel or groove or "opening" 90 facing distally away from the insertion tool for completely receiving a distal portion of the retractor (Figs. 10A, 10B, and 10C, col. 6, lines 27-51, col. 10, lines 34-67 and col. 11, lines 1-2).

Regarding claim 1, it is the Examiner's position that when the distal ring is engaged and expelled by push rod 95, "the distal ring intersects a primary central longitudinal axis of the insertion tool, namely, the longitudinal axis of pushrod 95.

Regarding claim 55, Mueller et al. disclose all elements of the claimed invention as discussed above. It is noted that pushrod 95 is monolithic.

Regarding claim 61, Mueller et al. disclose the insertion tool to have inward facing or tapered surfaces 90 that define a groove and an opening, the opening facing the wound opening during deployment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3775

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. (US 5,810,721).

Mueller et al. disclose all elements of the claimed invention except for the specific ranges of dimensions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Mueller et al. insertion tool with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments have been fully considered.

Applicant's arguments with respect to the rejections under 35 USC 112 first and second paragraphs of claim 58 have not been overcome, as discussed in this action.

Regarding the rejections under 35 USC 102(b) over Mueller et al., it is noted that Mueller et al. disclose an insertion tool which receives the distal ring 82 in an opening 90, wherein the opening faces distally away from the insertion tool (see Figs. 10B and 10C). Additionally, Mueller et al. disclose a monolithic shaft or push rod 95 that contacts distal ring 82 to expel the distal ring through opening 90 (col. 10, lines 52-67 and col. 11, lines 1-10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-

Art Unit: 3775

4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
November 9, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775